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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,431	06/05/2001	Karl Kolter	51497	5147

26474 7590 08/12/2003

KEIL & WEINKAUF
1350 CONNECTICUT AVENUE, N.W.
WASHINGTON, DC 20036

EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/12/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,431

Applicant(s)

KOLTER ET AL

Examiner

Blessing M. Fubara

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, request for continued examination under 37 CFR 1.114, declaration and preliminary amendment C filed 05/28/03.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 05/28/03 has been entered.

Claim Rejections - 35 USC § 112

2. The rejection of claims 1-25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendments to claims 1 and 17.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goertz et al. (US 4,801,460) and Ortega (US 4,837,032) in combination.

Goertz teaches a process of preparing sustained release theophylline composition where the process comprises heating a mixture of N-vinylpyrrolidone and vinyl acetate and theophylline at a temperature of 120 °C (examples 1 and 3). The composition is extruded and pressed into oblong tablets (examples 1 and 3). Goertz teaches that vinylpyrrolidone is a polymer (column 1, line 7) and that the binders are polymeric (and column 5, line 6). The composition further comprises lubricants (column 2, lines 17-31).

Goertz is silent on the molecular weight of the polyvinylpyrrolidone and the silence indicates that in Goertz polyvinylpyrrolidone of any molecular weight can be used. Secondly the instant claims heat the mixture at from 40 °C to 130 °C; Goertz discloses heating at from 50 °C to 180 °C and preferably at from 60 °C to 130 °C; and Goertz in examples 1 and 3 heats at 120 °C. It is clear that the range of heating temperature of the prior art overlaps that of the instant claim.

Goertz is silent on the presence of hydroxypropylcellulose in the composition. But Ortega teaches a sustained release composition comprising theophylline, polyvinyl acetate and polyvinylpyrrolidone, cellulose acetate phthalate and optionally lubricant (abstract). Ortega specifically teaches that water-soluble polymers or gel forming polymers are used in the composition and the water-soluble polymers or gel forming polymers in Ortega are polyvinylpyrrolidone and cellulose derivatives such as hydroxypropylcellulose (column 3, lines 49-53). Thus Ortega suggests that theophylline composition comprising polyvinyl acetate and hydroxypropylcellulose can be prepared. Ortega is relied upon for a teaching of theophylline, polyvinyl acetate and hydroxypropylcellulose.

Art Unit: 1615

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Goertz in combination with the teachings of Ortega. One having ordinary skill in the art would have been motivated to prepare a third composition comprising theophylline by combining the compositions of Goertz and Ortega because "it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose....[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). In the present case, theophylline compositions are prepared. Expectation of success is high because the individual prior art teaches theophylline composition and the expected result from combining the individual compositions to prepare a third theophylline composition is a composition that comprises polyvinylpyrrolidone, polyvinyl acetate and hydroxypropylcellulose.

A recitation particle size is not critical over the prior art in the absence of a showing. Since the prior art does not disclose the molecular weight of polyvinylpyrrolidone, polyvinylpyrrolidone having a wide range of molecular weight will work.

5. Claim 17-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Noda et al. (US 5,389,380) and Goertz et al. (4,801,460) in combination.

Noda teaches a composition comprising active ingredients, excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol (column 4, lines 43-47 and column 5, lines 63-65). Some of the active ingredients are theophylline, vitamins and analgesic.

Art Unit: 1615

Goertz teaches a process of preparing sustained release theophylline composition where the process comprises heating a mixture of N-vinylpyrrolidone and vinyl acetate and theophylline at a temperature of 120 °C (examples 1 and 3). The composition is extruded and pressed into oblong tablets (examples 1 and 3). Goertz teaches that vinylpyrrolidone is a polymer (column 1, line 7) and that the binders are polymeric (and column 5, line 6). The composition further comprises lubricants (column 2, lines 17-31).

Theophylline active agent is common to the compositions of both prior art. And because the compositions in the individual prior art have a common active ingredient, combined compositions can be prepared from the individual compositions. Noda does not teach a mixture of N-vinylpyrrolidone and vinyl acetate with theophylline or with analgesic or with vitamin. But Goertz teaches a mixture of N-vinylpyrrolidone and vinyl acetate with theophylline.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Noda in combination with the teaching of Goertz. One having ordinary skill in the art would have been motivated to prepare composition of Noda comprising excipients such as lactose, sucrose, sorbitol and mannitol and higher fatty acid or polyethylene glycol and active ingredients selected from theophylline, vitamins and analgesic in a mixture of N-vinylpyrrolidone and vinyl acetate since Goertz t prepared a composition comprising theophylline and a mixture of N-vinylpyrrolidone and vinyl acetate. Expectation of success is high because the individual prior art teaches individual compositions comprising theophylline.

The declaration submitted does not appear to compare the instant invention with the prior art because Goertz does not disclose the molecular weight of polyvinylpyrrolidone.

Art Unit: 1615

Secondly, the heating temperature of the instant claims and that of the prior art overlap and specifically the temperature of 120 °C lies within applicants' temperature of 40 °C to 130 °C and although 120 °C is closer to the upper limit of the temperature of the instant claims, nonetheless it is within the range. Thus, it is not clear how applicants arrived at the molecular weight that was used in the argument since Goertz assigned no molecular weight to the polyvinylpyrrolidone.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
Patent Examiner
Tech. Center 1600
August 9, 2003

